

Application No. 09/875,994
Response to Office Action dated April 7, 2004

REMARKS

New claim 37 has been added. Support for this new claim exists throughout the specification. No new matter has been added through this claim.

Applicant would like to thank Examiners Padmanabhan and Yu for the courteous and helpful Interview conducted July 1, 1994, in this case. During the Interview, Applicant explained how the Federal Circuit's recent decision in *Jansen v. Rexall Sundown Inc.*, 68 U.S.P.Q.2d 1154 (Fed. Cir. 2003) resolves the prior art issues in this case and requires that the currently pending prior art rejections be withdrawn. Applicant's explanation is repeated below.

In *Jansen*, the claims were directed to methods of treating or preventing macrocytic-megaloblastic anemia comprising administering effective amounts of folic acid and vitamin B₁₂ to humans in need thereof. *Jansen* at 1157. In interpreting these claims, the Federal Circuit ruled that the claims require the specific intent to achieve the claimed objective (treatment or prevention of macrocytic-megaloblastic anemia). Specifically, the Federal Circuit stated that:

. . . the claim preamble sets forth the objective of the method, and the body of the claim directs that the method be performed on someone 'in need.' In both cases, the claims' recitation of a patient or a human 'in need' gives life and meaning to preambles. [Citation omitted]. The preamble is therefore not merely a statement of effect that may or may not be desired or appreciated. Rather, **it is a statement of the intentional purpose for which the method must be performed**. We need not decide whether we would reach the same conclusion if either of the 'treating or

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preventing' phrase or the 'to a human in need thereof' phrase was not a part of the claim; **together, however, they compel the claim construction arrived at by both the district court and this court.**

Jansen at 1158 (emphasis added). The Federal Circuit further explained that:

the '083 patent claims are properly interpreted to mean that the combination of folic acid and vitamin B₁₂ **must** be administered to a human with a recognized need to treat or prevent macrocytic-megaloblastic anemia.

Jansen at 1158 (emphasis added).

Thus, according to the Federal Circuit, claims directed to methods of treatment to be performed on those in need of such treatment require the specific intent to effect such treatment.

In the present application, the pending claims are directed to methods of protecting keratin materials from the harmful effects of pollution by topically applying a composition containing a pollutant penetration limiting effective amount of phytanetriol to keratin materials in need of such protection. In accordance with the Federal Circuit's decision in *Jansen*, these claims must be interpreted to require the specific intent to effect protection of keratin materials from the harmful effects of pollution.

None of the cited art teaches or suggests such specific intent: that is, none of the prior art states that phytanetriol should be used to protect keratin materials from pollution's harmful effects. Moreover, none of the prior art constitutes a phytanetriol-containing product for which advertisements, instructions and/or directions relate to protecting keratin materials

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from pollution's harmful effects. In view of such fatal deficiencies, the prior art cannot teach or suggest the claimed methods.

Regarding the specific prior art rejections in this case, it is undisputed that Ribier I does not disclose using phytanetriol with the required specific intent of protecting keratin materials from pollution's harmful effects. Accordingly, the § 102 rejection based upon this reference is improper and should be withdrawn.

Regarding the §103 rejections, none of the cited references teaches or suggests the claimed methods which require applying phytanetriol to keratin materials with the intention of protecting such materials from polluton's harmful effects. Kuraray, the primary reference, merely discloses that phytanetriol protects hair and skin, but does not state how or from what such protection occurs. Thus, Kuraray neither teaches nor suggests using a pollutant penetration limiting effective amount of phytanetriol with the intent of protecting keratin materials from pollution's harmful effects. Rather, Kuraray's protection could come from any source such as, for example, phytanetriol's known moisturizing properties (arguably, moisturizing compositions "protect" hair and skin because they prevent dehydration) and could protect against any harmful effects. None of the secondary references, Ribier II, Bergman or Murad, compensate for Kuraray's deficiencies. None of these secondary references teach or suggest using a pollutant penetration limiting effective amount of phytanetriol with the intent of achieving the claimed protection. Thus, the combination of the cited references cannot yield the invention methods and, thus, cannot render them obvious. Accordingly, the rejections under § 103 are improper and should be withdrawn.

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During the Interview, the Examiners indicated their belief that the prior art inherently resulted in the claimed methods, thereby rendering such methods unpatentable. Such an inherency argument is inapplicable in this case.

In *Jansen*, the Federal Circuit discussed its earlier decision in *Rapoport v. Dement*, 254 F.3d 1053 (Fed. Cir. 2001) (copy enclosed). In *Rapoport*, the claims were directed to methods of treating sleep apneas comprising administering an effective amount of an azapirone compound to a patient in need of such treatment. In *Jansen*, the Federal Circuit characterized its *Rapoport* decision as follows:

We rejected [the argument that prior art disclosing treatment of a symptom of sleep apnea actually disclosed treatment of sleep apnea in *Rapoport*], stating, ‘There is no disclosure in the [prior art reference that the compound] is administered to patients suffering from sleep apnea *with the intent to cure the underlying condition.*’ Thus, the claim was interpreted to require that the method be practiced with the intent to achieve the objective stated in the preamble.

Jansen at 1157 (emphasis in original).

In *Rapoport*, the Federal Circuit addressed the issue of inherency (that is, whether prior art related to treating symptoms of sleep apnea inherently anticipated the claimed methods of treating sleep apnea). The Federal Circuit rejected this argument on two independent grounds.

First, and most importantly, the Federal Circuit noted that prior art did not disclose administering the compound to patients suffering from sleep apnea. *Rapoport* at 1062. Thus, as noted in *Jansen*, the prior art did not disclose administering the compound to patients

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suffering from sleep apnea “*with the intent to cure the underlying condition.*” Similarly, prior art which does not disclose applying a pollutant penetration limiting effective amount of phytanetriol to keratin materials in need of protection from pollution’s harmful effects cannot inherently anticipate or render obvious the claimed invention. For this reason alone the prior art rejections are improper and should be withdrawn.

The second independent ground was that it had not been demonstrated that the prior art regimen would necessarily result in treating sleep apnea even assuming such a regimen were administered to one suffering from sleep apnea. *Rapoport* at 1062-63. Similarly, and as set forth in the Appeal Brief filed in this case, reproducing the cited prior art in this case would not necessarily result in practicing the claimed methods. For this reason as well the prior art does not inherently anticipate or render obvious the claimed invention.

In view of the above, Applicant respectfully requests that all rejections under 35 U.S.C. §§ 102 and 103 be withdrawn.

The Office Action also rejected claims 1-24 and 26-31 under 35 U.S.C. § 112, first paragraph, as not being enabled for all pollutants and all keratin materials, and claims 1-23 and 26-28 under 35 U.S.C. § 112, second paragraph, as being indefinite due to the presence of the phrase “harmful effects.” In view of the following comments, Applicant respectfully requests reconsideration and withdrawal of these rejections.

Regarding the indefiniteness rejection, the specification (for example, pages 1-2) identifies several harmful effects associated with pollutants (for example, promoting desquamation of keratin materials, making keratin materials dull and dirty, reducing cellular defenses against free radicals, affecting cell respiration, reducing hair vigor, increasing sebum

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flow, increasing allergy and irritation problems, etc.). Applicant respectfully submits that one skilled in the art, given this extensive list of harmful effects as well as general knowledge which exists concerning the deleterious effects which pollution has on humans, would readily understand what the phrase "harmful effects" means in connection with pollution. In other words, the phrase "harmful effects" is definite when used in this context. In view of this, Applicant respectfully requests that the rejection under 35 U.S.C. § 112, second paragraph, be withdrawn.

Regarding the enablement rejections, the examples in the present application demonstrate that phytanetriol functions by limiting pollution adhesion onto/penetration into keratin material. The present application also teaches (1) that this functionality is the same regardless of the pollutant or keratin material, (2) that various types of pollutants (atmospheric pollutants including, for example, gases and heavy metals) and keratin materials (hair, skin, scalp, fingernails) exist, and (3) how to apply phytanetriol to achieve the desired protection. Thus, the present application teaches how to protect against the harmful effects of pollutants on any keratin material by limiting pollution adhesion/penetration.

Applicant respectfully submits that one skilled in the art, based on this disclosure as well as general knowledge concerning pollutants and the relative functions/activities of keratin materials, would be able to determine how to protect keratin materials from the harmful effects of pollution including determining which keratin materials need protection from which of pollution's harmful effects.¹

¹ All keratin materials suffer harmful effects from pollution. For example, all keratin materials are made dull and dirty by pollution. Merely because certain keratin materials (such as fingernails) may not suffer as many harmful effects as other keratin materials (such as

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In making the enablement rejections, the Office Action has effectively stated that Applicant enables only that which he has exemplified. Such a narrow, limited view of enablement is not only unfair but also contrary to well-settled law. Applicant cannot be expected to exemplify each and every combination before satisfying the enablement requirement. Such expectations would be unduly burdensome and time consuming. Rather, to satisfy the enablement requirement, Applicant must provide a disclosure which, if followed, would enable one skilled in the art to practice the claimed invention. As discussed above, Applicant has provided such an enabling disclosure. The fact that Applicant has exemplified his invention by demonstrating phytanetriol's ability to limit radiolabeled particles' adhesion onto/penetration into skin does not mean that Applicant's invention is limited radiolabeled particles and skin.

Finally, Applicant notes that the Office Action admits that the specification is enabling where the keratin material is skin. Accordingly, the enablement rejection is improper and should be withdrawn for existing claims 28 and 31 as well as new claim 37.

In view of the above, Applicant respectfully requests that the rejections under 35 U.S.C. § 112 be reconsidered and withdrawn.

The Office Action also rejected claims 1-24 and 26-31 under the judicially created doctrine of double patenting over claims 1-30 of co-pending application serial no. 09/875,993. Although Applicant disagrees with this double patenting rejection, solely to

skin) does not mean that the keratin materials do not suffer harmful effects. One skilled in the art could easily determine which keratin materials are subject to which harmful effects of pollution.

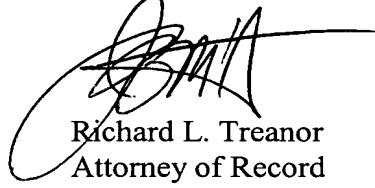
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expedite prosecution in this case Applicant intends to file a Terminal Disclaimer upon indication that all other rejections have been withdrawn.

Applicant believes that the present application is in condition for allowance. Prompt and favorable consideration is earnestly solicited.

Respectfully submitted,

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